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SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF BROOME

Index No.: EFCA2017001103

KEVIN O'NEIL,

Plaintiff,

-against-

SUMMONS

ARGON MEDICAL DEVICES, INC.;
REX MEDICAL, L.P.,

Defendants.

TO THE ABOVE NAMED DEFENDANTS:

YOU ARE HEREBY SUMMONED to answer the complaint in this action and to serve a copy of your answer, or, if the complaint is not served with this summons, to serve a notice of appearance, on the Plaintiff's attorney within 20 days after the service of this Summons, exclusive of the day of service (or within 30 days after the service is complete if this summons is not personally delivered to you within the State of New York); and in case of your failure to appear or answer, judgment will be taken against you by default for the relief demanded in the complaint.

Dated: New York, New York
May 16, 2017

MARC J. BERN & PARTNERS LLP
Attorneys for Plaintiffs

By: _____

Debra Humphrey
One Grand Central Place
60 East 42nd Street, Suite 950
New York, New York 10165
(212) 702-5000

DEFENDANTS' ADDRESSES:
ARGON MEDICAL DEVICES, INC.,
5151 Headquarters Drive., Suite 201
Plano, Texas 75024

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REX MEDICAL, L.P.
1100 Hector Street, Suite 242
Conshohocken, Pennsylvania 19428

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SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF BROOME

----------X Index No.:

KEVIN O'NEIL,

Plaintiff,

-against-

VERIFIED COMPLAINT

ARGON MEDICAL DEVICES, INC.;
and REX MEDICAL, L.P.,

JURY TRIAL DEMANDED

Defendants.

----------X

Plaintiff, KEVIN O'NEIL ("Plaintiff"), by and through his counsel, MARC J. BERN & PARTNERS, LLP, hereby sues Defendants ARGON MEDICAL DEVICES, INC., and REX MEDICAL, L.P., (collectively "Defendants") and alleges as follows:

PARTIES

1. Plaintiff, KEVIN O'NEIL, is a resident of New York, and currently resides at 24 Cezar St., 2nd Floor, Binghamton, Broome County, New York.

2. Plaintiff has suffered and continues to suffer substantial injury resulting from his implantation of the Argon Option™ Filter Inferior Vena Cava ("Option IVC Filter").

3. Defendant Argon Medical Devices Inc. ("Argon Medical") is a Delaware corporation duly organized and existing under the laws of Delaware, with its corporate headquarters located in Texas at 5151 Headquarters Drive, Suite 201, Plano, Texas.

4. Defendants Rex Medical Inc., operating as Rex Medical L.P. ("Rex Medical") is a Conshohocken, Pennsylvania company, duly organized and existing under the laws of

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Pennsylvania, with corporate headquarters located at 1100 Hector Street, Suite 242, Conshohocken, Pennsylvania. Rex Medical Inc., has conducted business in and derived substantial revenue from sale of its products, including Defendants' IVC filters, in New York.

5. Argon Medical Devices Inc., and Rex Medical, at all times relevant to this action, designed, set specification for, manufactured, prepared, compounded, assembled, processed, marketed, distributed and sold the Option™ IVC Filter system, which was thereafter implanted in patients throughout the United States and is the subject of this present lawsuit.

6. At all times mentioned herein, each of the Defendants was the representative, agent, employee, or alter ego of the other Defendant and in doing the things alleged in this Complaint was acting within scope of its authority.

7. "Argon Medical Devices" and "Rex Medical" or "Defendants" includes any and all parent companies, subsidiaries, affiliates, divisions, franchises, partners, joint ventures, and organizational units of any kind; the predecessors, successors, and assigns; their officers, directors, employees, agents, representatives; and any and all other persons acting on their behalf.

8. Argon Medical Devices, Inc., and Rex Medical L.P. and its affiliates are collectively referred to as "Defendants."

JURISDICTION AND VENUE

9. This Court has original jurisdiction of this civil action because the matter in controversy exceeds the sum or value of $25,000.

10. This Court has personal jurisdiction over Defendants pursuant to CPLR § 301 because Defendants are present and doing business within New York. Defendants are and were at all relevant times authorized to conduct business in New York and Defendants conducted

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such business within the state, including the performance of acts that caused or contributed to the harm giving rise to this action.

11. Venue is properly set in Broome County pursuant to CPLR § 503 because Plaintiff currently and at all relevant times resided in this county.

GENERAL FACTUAL ALLEGATIONS

12. The inferior vena cava ("IVC") is a vein that returns blood to the heart from the lower extremities. In certain individuals, blood clots or thrombi travel from the blood vessels in the leg and pelvis, through the IVC and into the lungs, causing a pulmonary embolism ("PE"). Such thrombi can also develop in the deep leg veins and are referred to a deep vein thrombosis ("DVT"). PEs are dangerous and can often result in death.

13. Individuals who are at risk of clotting are often treated with anticoagulants such as Heparin, Warfarin or Lovenox to reduce the risk.

14. For individuals who are at high risk for PE/DVT or for whom anticoagulants are contraindicated, doctors may recommend implantation of an IVC filter to reduce the risk of a thrombotic event.

15. An IVC filter is a medical device that is designed to prevent blood clots from traveling from the lower extremities to the heart and lungs. It is inserted into the IVC and works by trapping and filtering clots that form in the lower portions of the body.

16. The first transvenous method of interrupting bloods clots in the IVC was developed in 1967 with the advent of the Mobin-Uddin umbrella filter followed by the Greenfield IVC filter in 1973. These are permanent filters with no retrieval option.

17. Concerns over long-term complications of permanent IVC filers, particularly in patients in need of PE prophylaxis with a temporary contraindication to anticoagulation, has led

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to the development of temporary, retrievable filters. Beginning in or around 2003, medical device manufacturers also began marketing optional or retrievable IVC filters. These filters are designed to be removed from a patient when the risk of PE/DVT has passed. They were not designed to remain inside the IVC indefinitely.

18. Argon Medical and Rex Medical design, research, develop, manufacture, test, market, advertise, promote, distribute, and/or sell IVC filters that are marketed and sold as both a temporary/retrievable or permanent device to prevent, among other things, recurrent pulmonary embolism via placement in the vena cava.

19. The Option™ Vena Cava Filter systems, which were designed by Rex Medical, were the first retrievable vena cava filters approved for over-the-wire delivery. The nitinol filter can be guided thought the jugular or femoral access using a catheter that employs a color-coded filter introduction cartridge. The filter features an apex design and retention anchor system to optimize clot caption.

20. The Defendants applied for U.S. Food and Drug Administration ("FDA") clearance to market their Option IVC filter and/or its components under Section 510(k) of the Medical Device Amendment.

21. On or about June 4, 2009, the Defendants obtained FDA clearance to market the Option IVC filters under Section 510(k) of the Medical Device Amendment.

22. Section 510(k) allows for the marketing of medical devices, so long as the medical device is deemed substantially equivalent to other legally marketed predicate devices without formal review for the safety of efficacy of the device.

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23. The Defendants obtained FDA clearance under Section 510(k), and therefore bypassed the requirement to have the Option IVC filter independently evaluated by the FDA or its experts.

24. Argon conducted an internal, single-arm, multicenter clinical trial, which enrolled 100 health male subjects with a median age of 59 years, designed to evaluate the efficacy and safety of the Option™ IVC Filters.

25. The average implantation period of the subjects tested within Argon's internal study was 67 days.

26. After the median 67-day implantation period, removal or intervention was achieved without medical complication on 88% of subjects. The remaining 12% of subjects experienced complications ranging from migration of the device, embolization, symptomatic thrombosis and other complications requiring complex revision or removal. During the clinical study, of all surgical attempts at removal, 92% were successful, and 8% of subjects were unable to have the device removed from their body due to migration or complication of placement.

27. The Argon Option Vena Cava Filters are specifically designed for use as both a permanent or a temporary implant, as tested by Argon Medical's Principal Investigator, Dr. Matthew Johnson, who testified to the device' safety and efficacy when used both as a permanent and temporary filer in patients with increased risk of pulmonary embolism.

28. The Defendants' contention that the Option™ IVC filter is intended for multifunction (both temporary and long-term use), has been presented to the medical community, in forums such as the Annual Meeting of the Society of Interventional Radiologists. Dr. Matthew Johnson's findings based on the controlled clinic trial were introduced to defend the long-term sustainability of the Option IVC filter, making it more

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versatile than other IVC filters in market, which have largely transitioned to retrievable models only.

29. In August 2010, the U.S. Food & Drug Administration issued a warning against leaving inferior vena cava filters implanted in patients for extended periods due to their potential to cause adverse health complications. FDA warnings stated that retrievable IVC filters are for short-term use in patients at risk for pulmonary embolism, and implanting doctors are to remove the devices once the risk subsides. The FDA published studies concerning risks of doctors not retrieving IVC filters intended for short-term placement, exposing patients to problems caused by fractured implants.

30. The growing issue with the newer generation retrievable IVC filters that are designed to ward against the passage of blood clots as a hedge against pulmonary embolism for a finite period of time, then retrieved when the danger has passed. The FDA has since issued two alerts over the problematic retrievable filters, the first in 2010 following the receipt of some 900 adverse event reports in its reporting database. A further warning was issued four years later, at which point the FDA began urging doctors to remove retrievable IVC filters within one to two months once the danger for a pulmonary embolism had passed.

31. Despite the FDA alerts in 2010 and 2015 advising of the risks of long-term implantation and urging doctors to remove IVC filters after 2 months, Defendants' continued to market their Option™ IVC filter for both temporary and long-term use, defying the general recommendations of the FDA. Upon belief and information, instructional literature available to the medical community at the time of the Plaintiff's implant surgery still indicated that the Option™ IVC filter was safe for long-term use and no redactions or warnings were issued by Defendants' recommending removal of their devices after the temporary period lapsed.

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32. The FDA maintains an active compulsory database ("MAUDE Database") of adverse incidents reported by medical providers regarding pharmaceutical implants and devices. Every year, the FDA receives hundreds of medical device reports ("MDRs") of suspected device-associated deaths, serious injuries and malfunctions to contribute to the medical community's risk-benefit analysis of the use of certain devices. Several MAUDE reports have been published documenting serious incidences of malfunction of Defendants' Option and Option™ IVC filters.

33. A MAUDE incident report published in 2013 described an instance where Defendants' Argon filter became so deeply embedded in the vena cava that it was deemed irretrievable after an unsuccessful attempt. Another MAUDE incident documented the death of a patient after Defendants' Argon filter failed to properly function and caused multiple DVTs and thromboembolism leading to the patient's death. The FDA published at least six additional MDR reports in which patients suffered from various malfunctions Defendants' IVC filter ranging from fracture of the device, perforation of the vena cava, and death.[1] Of the publicly accessible reports furnished by the FDA, the most common malfunctions of Defendants' IVC filters include: irretrievability of the filters; device fractures; devices embedding into the walls of the vena cava and organs; and tilting of the devices, causing them to fail and actually cause PE and DVT, rather than prevent it.

34. In 2012, an annual report released by the American College of Chest Physicians "ACCP") titled *Evidence-Based Clinical Practice Guidelines on Antithrombic Therapy and Prevention of Thrombosis* concluded that "the routine use of IVC filters in addition to anticoagulants is not recommended for most patients with pulmonary embolism." The authoritative report further provided a caution against use if IVC filters because there are "no

[1] http://www.fdable.com/advanced_maude_query/6e18032bf9287e21ee23c0f560f09800

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large studies proving or disproving the efficacy of retrievable filters conclusively" or any indisputable medical clinical evident that this measure is safe for patients with pulmonary embolism of DVT.

35. Section 502(a) and 201(n) of the Federal Food Drug and Cosmetic Act ("the Act") requires Argon Medical and Rex Medical to fully and accurately disclose information relating to fracture or migration of the IVC filter, perforation of the heart, lungs, other vital organs, the wall of the vena cava and tissue, cardiac or pericardial tamponade, chest pain, shortness of breath, severe recurrent pulmonary embolisms and DVT, occlusion of clogging on the IVC filter, subsequent revision surgeries, difficulty or impossibility of removal, and other adverse effects of the Argon Option™ vena cava filter system and other labeling, and to include adequate warnings concerning these and other risks in promotional materials for Defendants' vena cava filters.

36. The Act also prohibits Defendants from minimizing these risks and promulgating misleading claims that the Argon Option™ vena cava filter system is safer than the other IVC filters on the market or that IVC filters in general are a safer long-term alternative to anticoagulant therapies.

PLAINTIFF'S SPECIFIC FACTUAL ALLEGATIONS

37. On or about December 12, 2011, Plaintiff KEVIN O'NEIL was treated at UHS Wilson Hospital located at 38-57 Harrison Street, Johnson City, New York for treatment of intracranial bleeds, including a basal artery bleed after undergoing a surgical procedure on his knee. Due to his inability to coagulate, Dr. Julie Miller deemed that it was medically necessary to order a surgical intervention to treat these conditions.

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38. On or about December 13, 2011, KEVIN O'NEIL underwent a surgical procedure to insert Defendants' Option™ IVC Filter at UHS Wilson Hospital. The IVC Filter implant procedure was conducted by surgeon, Mark J. Brennan, D.O. The Argon Option™ IVC Filter was inserted into the groin access and deployed through the femoral vein with good positioning into the vena cava at the L2 level.

39. The Option™ IVC Filter implanted in the Plaintiff on or about May 5, 2015 was designed by Rex Medical, L.P. and manufactured by Argon Medical Devices, Ref No: 352508070, Lot No: 838187, as positively identified on surgical reports, on the implant identification sticker and in medical records transcribed by Mark J. Brennon.

40. Upon information and belief, the Argon Option™ IVC Filter was implanted and utilized in accordance with Defendants' specific instructions, guidelines, and directives.

41. The Plaintiff was never considered for revision or removal of the device by any medical professionals.

42. Plaintiff inquired about the Argon Option filter remaining in his body, citing that he has stomach pain that he thinks may be attributable to a migrated device. KEVIN O'NEIL was informed that after such an extended implantation period, retrieval of the device would be difficult, if not impossible.

43. As of the present case, the Plaintiff still has the Defendants' Option™ IVC filter implanted in his body. This device has been implanted in Plaintiff's body for more than five years.

44. The most recent alert issued by the FDA regarding IVC filters strongly advises physicians to remove patient's filters within two months of implantation or when the issues of DVT and PE have diminished. The Plaintiff's implant, remaining within his body for an excess

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of five years, is considered a long-term implant, and constitutes a constant and imminent threat of death, migration, thrombosis, blockage or other life-threatening side effects (noted in the FDA alerts about removable IVC filters.)

45. As a direct and proximate result of the Option™ IVC Filter, Plaintiff suffered, is suffering and/or will continue to suffer from injuries including the possible risk of migration of the filter to the other parts of the vena cava, heart or other organs, DVT, blood clots, fracture or breakage of the filter and other complications.

46. As a direct and proximate result of the wrongful acts and omissions of Defendants, KEVIN O'NEIL has suffered economic damages, severe and possibly permanent injuries, and emotional distress. Plaintiff has also endured and continues to suffer the mental anguish and psychological trauma of living with this defective product implanted in his body and unable to be retrieved.

CLAIM I – NEGLIGENCE

47. Plaintiff repeats, reiterates, and re-alleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

48. Defendants had a duty to exercise reasonable case in the design, research, manufacture, marketing, testing, advertisement, supply, promotion, packaging, sale, and distribution of the Option™ IVC Filter, including the duty to take all reasonable steps necessary to manufacture and sell a product that was not defective and unreasonable dangerous to consumers and users of the product.

49. Defendants has a duty to warn health care providers and users of the risks, dangers and adverse side effects of implantation of the Option™ IVC Filter.

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50. Defendants knew or should have known that the Option™ IVC Filters were unsafe when used as designed and manufactured and failed to exercise due diligence and care and were otherwise negligent in the design, manufacture and marketing of this device, including the failure to adequately test the product and the failure to provide adequate warnings to health care providers and consumers of the device. This is especially true with regards to the lack of warning provided to heath care providers regarding the duration and long term use of the device.

51. Defendants continued to manufacture and market its product despite the knowledge, whether direct or ascertained with reasonable care, that the Argon Option™ IVC Filter posed a serious risk of bodily harm to consumers.

52. The conduct of Argon Medical Devices Inc. and Rex Medical L.P. in this matter was intentional, wanton, willful and outrageous beyond all standards of common decency and in reckless disregard and callous indifference to the public, the users of the Argon Option™ IVC Filter, and the Plaintiff.

53. As a direct and proximate result of the wrongful acts and omissions of Defendants, Plaintiff has suffered economic damages, severe and possibly permanent injuries, and emotional distress. Plaintiff has also endured and continues to suffer the mental anguish and psychological trauma of living with this defective product implanted in his body and unable to be retrieved.

WHEREFORE, Plaintiff, KEVIN O'NEIL demands judgement against Defendants and request compensatory damages for past, present and future pain and suffering, medical costs and expenses, lost wages, pre-judgement and post-judgement interest as allowed by law, costs of suit

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and attorneys' fees, as allowed by law, punitive damages, and all such other relief as the Court deems just and proper; and further, demands a trial by jury of all issues so triable.

CLAIM II STRICT PRODUCTS LIABILITY – DEFECTIVE DESIGN

54. Plaintiff repeats and re-alleges each and every allegation previously set forth herein.

55. The Argon Medical Option™ IVC Filter designed, marketed, manufactured and distributed by the Defendant was defective and not reasonably safe due to its improper, inadequate, and defective design.

56. Defendants are strictly liable in tort to Plaintiff for designing, marketing, manufacturing and distributing the Argon Option Vena Cava filter that was implanted into the Plaintiff.

57. Defendants designed, researched, developed, manufactured, tested, labeled, advertised, promoted, marketed, sold, supplied, and/or distributed the Option™ IVC Filter.

58. The Option™ IVC Filter was expected to, and did, reach the intended consumers, handlers, and persons receiving the product with no substantial change in the condition in which the product was designed, produced, manufactured, sold, distributed, labeled, and marketed by Defendants.

59. The Option™ IVC Filter was manufactured, designed, marketed, labeled and sold in a defective condition, for use by Plaintiff's physicians and/or healthcare providers, and all other consumers of the product, making the product unreasonably dangerous.

60. The Option™ IVC Filter, as designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by Defendants was defective in design and formulation in that when it left the hands of the manufacturers, suppliers, and distributors,

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the foreseeable risks of harm caused by the product exceeded the claimed benefits of the product.

61. Defendants' Option™ IVC Filter, as designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by Defendants was defective in design and formulation, because when it left the hands of Defendants, the product was unreasonably dangerous and was also more dangerous than expected by the ordinary consumer.

62. At all times relevant to this action, Defendants knew and had reason to know that its Option™ IVC Filter was inherently defective and unreasonably dangerous as designed, formulated, and manufactured by Defendants, and when used and administered in the form manufactured and distributed by Defendants, and in the manner instructed by Defendants to be used and administered to the Plaintiff and other consumers.

63. Plaintiff's physicians and/or healthcare providers used and administered the Option™ IVC Filter for the purpose intended by Defendants, and in a manner normally intended to be used and administered, namely for implantation of the IVC to prevent PE. Defendants had a duty to design, create, and manufacture products that were reasonably safe and not unreasonably dangerous for their normal, common, and intended use. Defendants' product was not reasonably fit, suitable, or safe for its anticipated use, and safer, reasonable alternative designs existed and could have been utilized. Reasonably prudent manufacturers would not have placed the product in the stream of commerce with knowledge of these design flaws.

64. Defendants designed, developed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed a defective product that created an unreasonable risk of serious harm to the health, safety, and well-being of the Plaintiff and other consumers.

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Defendants is therefore strictly liable for the Plaintiff's injuries and damages sustained proximately caused by his use of the product.

65. Plaintiff, KEVIN O'NEIL, could not, by the exercise of reasonable care, discover the defective condition of Defendants' product and/or perceive its defective dangers prior to its administration by his physicians and/or healthcare providers.

66. As a direct and proximate result of the wrongful acts and omissions of Defendants, KEVIN O'NEIL has suffered economic damages, severe and possibly permanent injuries, and emotional distress. Plaintiff has also endured and continues to suffer the mental anguish and psychological trauma of living with this defective product implanted in his body and unable to be retrieved.

WHEREFORE, Plaintiff, KEVIN O'NEIL demands judgment against the Defendant, and requests compensatory damages for past, present, and future pain and suffering, medical costs and expenses, lost wages; prejudgment and post-judgment interest as allowed by law, costs of suit and attorneys' fees, as allowed by law, punitive damages, and any and all such other relief as the Court deems just and proper; and further, demands a trial by jury of all issues so triable.

CLAIM III – STRICT PRODUCTS LIABILITY – FAILURE TO WARN

67. Plaintiff repeats and re-alleges each and every allegation previously set forth herein.

68. Defendants designed, researched, developed, manufactured, tested, labeled, advertised, promoted, marketed, sold, supplied, and/or distributed the Option™ IVC Filter.

69. The Option™ IVC Filter was expected to, and did, reach the intended consumers, handlers, and persons receiving the product with no substantial change in the

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condition in which the product was designed, produced, manufactured, sold, distributed, labeled, and marketed by Defendants.

70. The Option™ IVC Filter was manufactured, designed, marketed, labeled and sold in a defective condition, for use by the Plaintiff's physicians and/or healthcare providers and all other consumers of the product, making the product unreasonably dangerous.

71. Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released into the stream of commerce its Option™ IVC Filter and in the course of same, directly advertised or marketed the product to consumers or persons responsible for consumers, and therefore had a duty to warn of the risks associated with the use of its product.

72. Defendants' Option™ IVC Filter, as designed, researched, developed, manufactured, tested, advertised, promoted, marketed, sold, labeled, and distributed by Defendants, was defective due to the product's inadequate warnings and instructions. Defendants knew, or should have known, and adequately warned that its product created a risk of serious and dangerous side effects, including but not limited to, the migration of the filter to the other parts of the vena cava, heart or other organs, DVT, blood clots, fracture or breakage of the filter and other complications.

73. The product was under the exclusive control of Defendants and was unaccompanied by appropriate and adequate warnings regarding the risk of severe and permanent injuries associated with its use, including, but not limited to, the migration of the filter to the other parts of the vena cava, the heart or other organs. The warnings given did not accurately reflect the risk, incidence, symptoms, scope or severity of such injuries to the consumer.

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74. Notwithstanding Defendants' knowledge of the defective condition of its product, Defendants failed to adequately warn the medical community and consumers of the product, including the Plaintiff and his healthcare providers, of the dangers and risk of harm associated with the use and administration of its Option™ IVC Filter.

75. Defendants downplayed the serious and dangerous side effects of its product to encourage sales and use of the product; consequently, Defendants placed its profits above its customers' safety.

76. The product was defective when it left the possession of Defendants in that it contained insufficient warnings to alert the Plaintiff and/or his healthcare providers to the dangerous risks and reactions associated with it, including possible migration of the filter to the other parts of the vena cava, the heart or other organs, deep vein thrombosis (DVT), blood clots, fracture or breakage of the filter and other complications.

77. Defendants knew or should have known that the Option™ IVC Filters were defective and dangerous and showed reckless indifference to or conscious disregard for the Plaintiff's safety by failing to provide proper warnings to the public and the medical community. Plaintiff received Defendants' Option™ IVC Filter as intended or in a reasonably foreseeable manner.

78. Defendants, as a manufacturer of pharmaceutical products, is held to the level of knowledge of an expert in the field and, further, Defendants had knowledge of the dangerous risks and side effects of its product.

79. Plaintiff KEVIN O'NEIL did not have the same knowledge as Defendants and no adequate warning was communicated to his physicians and/or healthcare providers.

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80. Defendants had a continuing duty to warn consumers or persons responsible for consumers of its Option™ IVC Filter, including the Plaintiff, of the dangers associated with its product, and by negligently and/or wantonly failing to adequately warn of the dangers of the use of its product, Defendants breached its duty.

81. Although Defendants knew, or should have known, of the defective nature of its Option™ IVC Filter, it continued to design, manufacture, market, and sell its product without providing adequate warnings and instructions concerning the use of its product so as to maximize sales and profits at the expense of the public health and safety, in knowing, conscious, and deliberate disregard of the foreseeable harm caused by its Option™ IVC Filter.

82. Upon information and belief, the Option™ IVC Filter as manufactured and supplied by Defendants, was further defective due to inadequate post-market warnings or instructions because after Defendants knew, or should have known, of the risk of serious bodily harm from the administration of its Option™ IVC Filter, including, but not limited to, possible migration of the filter to the other parts of the vena cava, the heart or other organs, deep vein thrombosis ("DVT"), blood clots, fracture or breakage of the filter and other complications, Defendants failed to provide adequate warnings to consumers and/or their healthcare providers about the product, knowing the product could cause serious injury.

83. The Option™ IVC Filter, upon information and belief, as manufactured and supplied by Defendants, was defective due to inadequate post-market warnings or instructions when it left Defendants' control.

84. As a direct and proximate result of the wrongful acts and omissions of Defendants, KEVIN O'NEIL has suffered economic damages, severe and possibly permanent

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injuries, and emotional distress. Plaintiff has also endured and continues to suffer the mental anguish and psychological trauma of living with this defective product implanted in his body and unable to be retrieved.

WHEREFORE, Plaintiff, KEVIN O'NEIL demands judgment against the Defendant, and request compensatory damages for past, present, and future pain and suffering, medical costs and expenses, lost wages; prejudgment and post-judgment interest as allowed by law, costs of suit and attorneys' fees, as allowed by law, punitive damages, and any and all such other relief as the Court deems just and proper; and further, demands a trial by jury of all issues so triable.

CLAIM IV – BREACH OF EXPRESS WARRANTY

85. Plaintiff repeats, reiterates, and re-alleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

86. At the time of making such express warranties, Defendants knew and/or should have known that its Option™ IVC Filters did not conform to the express warranties and representations and that, in fact, its product was not safe and had numerous serious side effects, including the possibility of viral infection, of which Defendants had full knowledge and did not accurately or adequately warn.

87. Defendants expressed in their literature, advertisements, and promotions and through representations by their marketing team and sales agents that Option™ IVC Filters were safe, effective and fit for implantation into the IVC to prevent PE and DVT for which they were designed, manufactured and marketed.

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88. By making such representations, Defendants expressly warranted that the Option™ IVC Filters were safe and effective, and fit for the uses for which they were designed, marketed, manufactured and distributed.

89. As explained above, in fact, the Option™ IVC Filters were not safe, effective, fit nor proper for the use for which they were designed, manufactured and marketed.

90. Plaintiff, through his physicians and/or other healthcare providers, did rely on Defendants' express warranties regarding the safety and efficacy of their product in using the product.

91. Members of the medical community, including physicians and other healthcare professionals, relied upon Argon's representations and express warranties in connection with the use recommendation, description, and implantation of the Option™ IVC Filter.

92. As a direct and proximate result of the wrongful acts and omissions of Defendants, Plaintiff has suffered economic damages, severe and possibly permanent injuries, and emotional distress. Plaintiff has also endured and continues to suffer the mental anguish and psychological trauma of living with this defective product implanted in his body and unable to be retrieved.

WHEREFORE, Plaintiff, KEVIN O'NEIL demands judgment against the Defendants and request compensatory damages for past, present, and future pain and suffering, medical costs and expenses, lost wages; prejudgment and post-judgment interest as allowed by law, costs of suit and attorneys' fees, as allowed by law, punitive damages, and any and all such other relief as the Court deems just and proper; and further, demands a trial by jury of all issues so triable.

CLAIM V – BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY

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93. Plaintiff repeats and re-alleges each and every allegation previously set forth herein.

94. At all times relevant to this action, Defendants manufactured, compounded, portrayed, distributed, recommended, merchandised, advertised, promoted, and/or sold its Option™ IVC Filter for use.

95. Defendants knew of the intended use of its Option™ IVC Filters at the time Defendants distributed its product for use by the Plaintiff's physicians and healthcare providers, and impliedly warranted the product to be of merchantable quality and safe and fit for its intended use.

96. Defendants impliedly represented and warranted to the medical community, the regulatory agencies, and consumers, including the Plaintiff, his physicians, and his healthcare providers, that Option™ IVC Filter was safe and of merchantable quality and fit for the ordinary purpose for which the product was intended and promoted to be used.

97. Defendants' representations and implied warranties were false, misleading, and inaccurate because its product was defective, and not of merchantable quality.

98. Upon information and belief, on or around December 13, 2011 Plaintiff received and began using the Argon Option™ IVC Filter manufactured by Defendants.

99. Defendants impliedly warranted that the Option™ IVC Filter was merchantable pursuant to UCC § 2-314 and suitable for the ordinary purpose for which it was intended to be used for implantation into the IVC to prevent PE.

100. Defendants breached its implied warranty because its product were not merchantable nor reasonably suited for the ordinary purpose for which they were being used.

101. As a result, Defendants breached UCC § 2-314.

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102. As a direct and proximate result of the wrongful acts and omissions of Defendants, Plaintiff has suffered economic damages, severe and possibly permanent injuries, and emotional distress. Plaintiff has also endured and continues to suffer the mental anguish and psychological trauma of living with this defective product implanted in his body.

WHEREFORE, Plaintiff, KEVIN O'NEIL demands judgment against the Defendants and request compensatory damages for past, present, and future pain and suffering, medical costs and expenses, lost wages; prejudgment and post-judgment interest as allowed by law, costs of suit and attorneys' fees, as allowed by law, punitive damages, and any and all such other relief as the Court deems just and proper; and further, demands a trial by jury of all issues so triable.

CLAIM VI – BREACH OF IMPLIED WARRANTY OF FITNESS

103. Plaintiff repeats and re-alleges each and every allegation previously set forth herein.

104. At all times relevant to this action, Defendants manufactured, compounded, portrayed, distributed, recommended, merchandised, advertised, promoted, and/or sold its Option™ IVC Filter for use.

105. Defendants knew of the intended use of its Option™ IVC filters at the time Defendants distributed its product for use by the Plaintiff's physicians and healthcare providers, and impliedly warranted the product to be of merchantable quality and safe and fit for its intended use.

106. Defendants impliedly represented and warranted to the medical community, the regulatory agencies, and consumers, including the Plaintiff, his physicians, and his healthcare providers, that Option™ IVC filter was safe and of merchantable quality and fit for the ordinary purpose for which the product was intended and promoted to be used.

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107. Defendants impliedly warranted, pursuant to UCC § 2-315, that the Option™ IVC Filters were fit for a particular purpose for which they were being used, implantation into the IVC to treat DVT.

108. Defendants' Option™ IVC Filters were not fit for the particular purpose for which they were being used.

109. As a result, Defendants breached UCC § 2-315.

110. As a direct and proximate result of the wrongful acts and omissions of Defendants, Plaintiff has suffered economic damages, severe and possibly permanent injuries, and emotional distress. Plaintiff has also endured and continues to suffer the mental anguish and psychological trauma of living with this defective product implanted in his body.

WHEREFORE, Plaintiff, KEVIN O'NEIL demands judgment against the Defendants and request compensatory damages for past, present, and future pain and suffering, medical costs and expenses, lost wages; prejudgment and post-judgment interest as allowed by law, costs of suit and attorneys' fees, as allowed by law, punitive damages, and any and all such other relief as the Court deems just and proper; and further, demands a trial by jury of all issues so triable.

CLAIM VII – FRAUDULENT MISREPRESENTATION

111. Plaintiff repeats and re-alleges each and every allegation previously set forth herein.

112. Defendants engaged in commercial conduct by selling Option™ IVC Filters and misrepresented and omitted material information regarding this product by failing to disclose the known risks of their Option™ Filters and predecessor devices.

113. By failing to disclose the known dangers and risks of the Option™ IVC Filters and predecessor devices, Defendants engaged in unfair and deceptive consumer-oriented acts

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which intentionally, willfully, and knowingly, fraudulently misrepresented to the medical community, the FDA, and consumers, including the Plaintiff and his health care providers, that its Option™ IVC Filters had been adequately tested in clinical trials and was found to be safe and effective.

114. Defendants knew or believed at the time it made its fraudulent misrepresentations, that its misrepresentations were false and fraudulent regarding the dangers and risks associated with use of its Option™ IVC Filters. Defendants made its fraudulent misrepresentations intentionally, willfully, wantonly, and with reckless disregarded and depraved indifference for the safety and well-being of the users of their product, such KEVIN O'NEIL.

115. Defendants' fraudulent misrepresentations were made with the intent of defrauding and deceiving the medical community, the Plaintiff, and the public, and also inducing the medical community, and the public, to recommend, dispense, and use Defendants' product.

116. As a direct and proximate result of the wrongful acts and omissions of Defendants, Plaintiff has suffered economic damages, severe and possibly permanent injuries, and emotional distress. Plaintiff has also endured and continues to suffer the mental anguish and psychological trauma of living with this defective product implanted in his body.

WHEREFORE, Plaintiff KEVIN O'NEIL demands judgment against the Defendants and request compensatory damages for past, present, and future pain and suffering, medical costs and expenses, lost wages; prejudgment and post-judgment interest as allowed by law, costs of suit and attorneys' fees, as allowed by law, punitive damages, and any and all such other relief as the Court deems just and proper; and further, demands a trial by jury of all issues so triable.

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COUNT VII – NEGLIGENT MISREPRESENTATION

117. Plaintiff repeats and re-alleges each and every allegation previously set forth herein.

118. Defendants had a duty to accurately and truthfully represent to the medical community, the FDA, and U.S. consumers, including Plaintiff, KEVIN O'NEIL, material information regarding this product by failing to disclose the known risks of their Option™ IVC Filters and predecessor devices. The truth regarding Defendants' claims that Defendants' product had been tested, and found to be safe and effective for its stated purposes. The misrepresentations made by Defendants, in fact, were false and Defendants was careless or negligent in ascertaining the truth of the representations at the time Defendants made the misrepresentations.

119. Defendants represented and promoted its Option™ IVC Filters as being safe and effective.

120. Defendants were aware of the risks of its Option™ IVC Filters and failed to communicate to the Plaintiff, KEVIN O'NEIL and other members of the general public, that the administration of this product could cause serious injury, including but not limited to, the migration of the filter to the other parts of the vena cava, the heart or other organs, DVT, blood clots, fracture or breakage of the filter and other complications.

121. Defendants failed to exercise ordinary care in making representations concerning its product and its manufacture, testing, quality assurance, quality control, and distribution in interstate commerce. Defendants negligently and/or carelessly misrepresented and intentionally concealed the truth regarding the risk of the product's unreasonable,

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dangerous and adverse side effects associated with the administration, use, and implantation of the product.

122. Defendants breached its duty in representing to the Plaintiff, his physicians and healthcare providers, and the medical community that Defendants' product did not carry the risk of serious side effects such as those stated above.

123. Defendants failed to warn the Plaintiff and other consumers, of the defective condition of the Option™ IVC filters, as manufactured and/or supplied by Defendants.

124. Defendants negligently misrepresented material facts about its Option™ Filters in that it made such misrepresentations when they knew or reasonably should have known of the falsity of such misrepresentations. Alternatively, Defendants made such misrepresentations without exercising reasonable care to ascertain the accuracy of these representations.

125. The above misrepresentations were made to Plaintiff, KEVIN O'NEIL, as well as the general public.

126. Plaintiff, KEVIN O'NEIL, and his healthcare providers and physicians, justifiably relied on Defendants' misrepresentations.

127. As a direct and proximate result of the wrongful acts and omissions of Defendants, Plaintiff has suffered economic damages, severe and possibly permanent injuries, and emotional distress. Plaintiff has also endured and continues to suffer the mental anguish and psychological trauma of living with this defective product implanted in his body.

WHEREFORE, Plaintiff KEVIN O'NEIL demands judgment against the Defendants, and request compensatory damages for past, present, and future pain and suffering, medical costs and expenses, lost wages; prejudgment and post-judgment interest as allowed by law,

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costs of suit and attorneys' fees, as allowed by law, punitive damages, and any and all such other relief as the Court deems just and proper; and further, demands a trial by jury of all issues so triable.

PUNITIVE DAMAGES

128. Plaintiff re-alleges each and every allegation in this Complaint and incorporates each allegation into this Count, as if set forth at length, in its entirety.

129. Plaintiff is entitled to an award of punitive and exemplary damages based upon Defendants' intentional, willful, knowing, fraudulent, malicious acts, omissions, and conduct, and their complete and total reckless disregard for the public safety and welfare.

133. Defendants had knowledge of, and were in possession of evidence demonstrating that, the Option™ filter was defective and unreasonably dangerous and had a substantially higher failure rate than did other similar devices on the market. Yet, Defendant failed to:

a. Inform or warn Plaintiff or his health care providers of the dangers;

b. To establish and maintain an adequate quality and post-market surveillance system; and

c. Recall the filter from the market.

134. Argon and Rex Medical acted to serve their own interests and having reasons to know and consciously disregarding the substantial risk that their product might kill or significantly harm patients, or significantly injure the rights of others, and consciously pursued a course of conduct knowing that such conduct created a substantial risk of significant harm to other persons.

135. As a direct, proximate, and legal result of Defendants' acts and omissions a described herein, and KEVIN O'NEIL suffered serious injury

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CONCLUSION AND PRAYER

WHEREFORE, Plaintiff request trial by jury and that the Court grant them the following relief against Defendant on all counts of the Complaint, including:

(A) Money damages representing fair, just and reasonable compensation for his common law and statutory claims in excess of $50,000.00;

(B) Lost Wages;

(C) Punitive and/or Treble Damages pursuant to state law;

(D) Disgorgement of profits and restitution of all costs;

(E) Attorneys' fees pursuant to state law;

(F) Pre-judgement and post-judgement interests as authorized by law on the judgements which enter on Plaintiffs' behalf;

(G) Cost of suit;

(H) Delay Damages; and

(I) Such other relief as is deemed just and proper.

WHEREFORE, Plaintiff demands judgment against the Defendants herein in an amount that exceeds the jurisdictional limitations of all lower courts that would otherwise have jurisdiction over this action, together with the interest, costs and disbursements of same allowed by law.

Dated: New York, New York
May 10, 2017

MARC J. BERN & PARTNERS LLP
Attorneys for Plaintiff

Debra Humphrey